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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/302,863	04/30/1999	RAYMOND G. GOODWIN	2519	7568
22932	7590	05/03/2004	EXAMINER	
IMMUNEX CORPORATION LAW DEPARTMENT 1201 AMGEN COURT WEST SEATTLE, WA 98119				ROMEON, DAVID S
		ART UNIT		PAPER NUMBER
		1647		

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/302,863	GOODWIN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	David S Romeo	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 05 February 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 15-39 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 29,30 and 32 is/are allowed.

6)  Claim(s) 15-28,31 and 33-39 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action 5 has been withdrawn pursuant to 37 CFR 1.114.

Claims 15-39 are pending and being examined.

10 **New Formal Matters, Objections, and/or Rejections:**

### ***Claim Rejections - 35 USC § 112***

Claims 15-28, 31, 33-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method screening a test compound comprising forming a composition comprising, with reference to claim 15, (i)(a)-(b) and 15 (ii)(a)-(c), does not reasonably provide enablement for a method screening a test compound comprising forming a composition comprising, with reference to claim 15, (i)(c)-(d) and (ii)(d)-(e). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

20 Although the claims require that 15(i)(c)-(d) bind SEQ ID NO: 4 and that 15(ii)(d)-(e) bind SEQ ID NO: 2, the claims do not require that any of 15(i)(c)-(d) bind any of 15(ii)(d)-(e). The claims are further directed to or encompass a method of screening comprising forming a composition comprising a polypeptide encoded by a

nucleic acid molecule that is at least 90% identical SEQ ID NO: 1, wherein said polypeptide binds SEQ ID NO: 4, and a polypeptide encoded by a nucleic acid molecule that is at least 90% identical SEQ ID NO: 3, wherein said polypeptide binds SEQ ID NO:

2. Accordingly, the claims are directed to testing the interaction of a first genus of

5 polypeptides encoded by nucleic acid molecules at least 90% identical SEQ ID NO: 1,

wherein said first genus polypeptides binds SEQ ID NO: 4, with a second genus of

polypeptides encoded by nucleic acid molecules at least 90% identical SEQ ID NO: 3,

wherein said second genus polypeptides binds SEQ ID NO: 2. However, the claims do

not require that the first genus bind anything in the second genus except SEQ ID NO: 4

10 and the claims do not require that the second genus bind anything in the first genus

except SEQ ID NO: 2. It is noted that a given per cent identity at the nucleotide level

translate into a much lower level of sequence identity at the amino acid level. The first

and second genus encompass deletions, insertions, substitutions, additions, and

frameshifts to the encoded amino acid sequences. The problem of predicting protein

15 structure from sequence data and in turn utilizing predicted structural determinations to

ascertain functional aspects of the protein is extremely complex. While it is known that

many amino acid substitutions are generally possible in any given protein the positions

within the protein's sequence where such amino acid substitutions can be made with a

reasonable expectation of success are limited. Certain positions in the sequence are

20 critical to the protein's structure/function relationship, e.g. such as various sites or regions

directly involved in binding, activity and in providing the correct three-dimensional

spatial orientation of binding and active sites. These or other regions may also be critical

determinants of antigenicity. These regions can tolerate only relatively conservative

substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495).

However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue

5 experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. The art recognizes that function cannot be predicted from structure alone. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the

10 structure of a given protein from its amino acid sequence alone. See Bowie (U) page 1306, column 1, full paragraph 1, and Ngo (V) page 433, full paragraph 1, and page 492, full paragraph 2. Due to the quantity of experimentation necessary to generate the large

number of derivatives encompassed by the claims and screen same for activity or interactions, the lack of direction/guidance presented in the specification regarding which

15 structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make

20 and/or use the claimed invention in its full scope.

Applicant's arguments have been fully considered but they are not responsive to the present rejection.

Claims 15-28, 31, 33-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although the claims require that 15(i)(c)-(d) bind SEQ ID NO: 4 and that 15(ii)(d)-(e) bind SEQ ID NO: 2, the claims do not require 5 that any of 15(i)(c)-(d) bind any of 15(ii)(d)-(e), except for SEQ ID NO: 4, or that any of 15(ii)(d)-(e) bind any of 15(i)(c)-(d), except for SEQ ID NO: 2. Insofar as the claimed method is directed to a method of screening for compounds that affect an interaction, and to the extent that the claims do not require an interaction to take place, then the metes and bounds are not clearly set forth.

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### ***Conclusion***

Claims 29, 30, and 32 are allowable.

The claims are allowable over the prior art of record because obviousness cannot be predicated on what is not known at the time an invention is made, even if the 15 inherency of a certain feature is alter established.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (571) 272-0887.

20 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306  
AFTER FINAL (703) 872-9307

25 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647